Applying Tech: Cardiovascular, Part II

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How are you influencing cardiovascular devices?

John Beigel
Technical Expert and Member of the Board of Directors, MEDER Electronics

MEDER/Standex is currently involved with a new MEM reed sensor design that will reduce its board space from 1.17 square mm to approximately 0.5 square mm. The economy of scale integration will not only reduce the board space but will offer much lower manufacturing costs reducing the MEM reed sensor sell price. Since cardiovascular devices are implanted in the human body, life is critical. Since the reed sensor draws no power in its off state, it represents an ideal solution over semiconductor devices that require power draw 100% of the time. This greatly increases the life or survival time in the human body.

Brian McPherson
COO, Neovasc

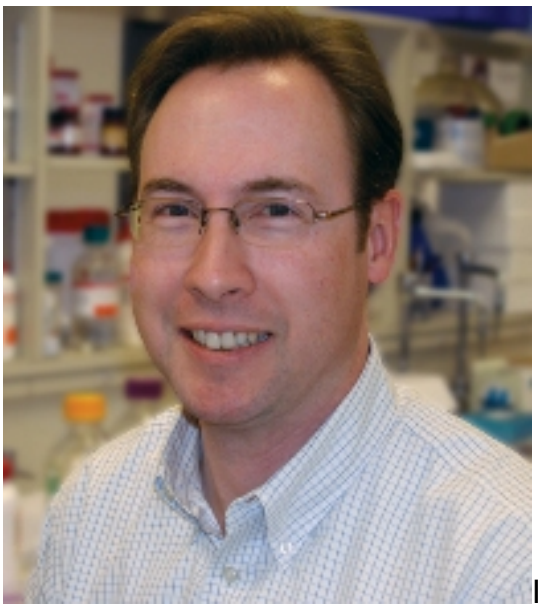
 Neovasc is the go-to company for valve designers needing pericardial tissue to support their heart valve programs. The advent of transcatheter aortic valve implantation (TAVI), often the last hope for patients suffering from severe aortic stenosis, has increased that need.

The acquisitions of CoreValve and Ventor Technologies by Medtronic, and that of Sadra Medical by Boston Scientific, ignited the dreams of every prosthetic heart valve designer and venture group. Many of these development programs hit a roadblock as they soon realized that pericardial tissue is an integral component in valve design and a raw material not easily obtainable.

Creating commercially available custom, medical device quality pericardial tissue, Neovasc enables design engineers to focus on design iterations instead of sourcing and preparing tissue. Neovasc eliminates the need to invest in costly animal by-product processing systems so that hard-earned capital can instead be directed at refining the function of the device, expediting the valve development program.

Neovasc’s pericardial tissue processing systems have withstood the rigors of the FDA and European notified body quality audits. An integral component of many successful heart valve programs, we’re committed to ensuring that this critical material is readily available to our clients.

Robert Hergenrother
Senior Director Research and Development, SurModics



It’s not the journey, it’s the destination. In the case of interventional cardiovascular devices, both the journey and the destination are vital. These devices need to navigate the tortuous pathways of the vasculature in order to access and treat complex distal lesions. Getting there isn’t always easy.

Low-friction coatings are critical for improving the delivery of balloon catheters and stents. Recently, there has been a growing interest among clinicians and regulators about the particulates created and left behind during procedures using these devices.

Although there are currently no regulations or universal standards around the “safe” level of particulate coming from devices during use, the general consensus is that less is preferable. Safety remains uppermost on the minds of device manufacturers and clinicians alike.

Given recent advances in low-friction coating technologies, device manufacturers can now optimize the best coatings for a particular device. Consideration should be given not only to the usual parameters—ease of application, durability, low friction/high lubricity—but also to particulate levels. Using the lowest particulate coatings available for a specific application can offer both performance and peace of mind.

Peter Gabriele
Director, Emerging Technology, Secant Medical

Regenerative medicine (RM) relies on the convergence of competencies in biotechnology and bioengineering, where researchers seek answers to the complexities of tissue engineering in cardiovascular care. An example of convergence of strategic technologies and resources for cardiovascular RM is advanced high definition 3D textile architecture (HD3DTA) used to create hollow-bodied organ scaffolds. The convergence of biomedical textile architecture with innovative fiber biomaterials offers controlled design of scaffold constructs.

The basic constructs in synthetic textile vascular graft repair can be transformed into biodegradable vascular tissue scaffolds with HD3DTA technology offering precision management of scaffold resorption with tissue growth with a host of FDA-approved synthetic, biodegradable polymers that allow more reliable bio-inspired structures to support tissue regeneration. The precision control of resorption of biomaterials supports tissue remodeling and encourages endogenous recruitment or the ability of in vivo cellular mechanisms to support the body’s natural self-regenerative process.

Biomedical HD3DTA enables managed degradation, microstructural repeatability, spatial geometry, and functional strength in organ regeneration. These factors illustrate the impact that the convergence of traditional textile engineering, combined with new biomaterials, offers for successful advances cardiovascular care and a potentially quicker time to market.

Donald M. Garcia
Director, Research & Development, Boyd Coatings Research Company Inc.

Coatings for cardiovascular guidewires require high performance technical coatings. Boyd Coatings, a medical grade coater, utilizes a premier coating using a base PTFE (Polytetrafluoroethylene) fluoropolymer resins made by various vendors to formulate its own PTFE coatings with exceptional properties.

Currently, PFOA (perfluorooctanoic acid) is used as a processing aid in the manufacture of the base PTFE resins. There is an EPA initiative to phase-out the use of PFOA, worldwide, by 2015. Boyd and its vendors have chosen to be proactive in coming up with alternative technologies to make a new generation of products and processes eliminating PFOA and its environmental impact without sacrificing product performance. While the official goal for PFOA phase-out is 2015, Boyd Coatings has set its own phase-out date of Spring 2013 in order to allow its medical customers time to conduct their due diligence with our-new PFOA free products and processes. Meanwhile, to avoid any negative impact of the phase-out to our medical customers, we are constantly monitoring and coordinating affected products for material availability of existing PTFE, and new PFOA-free PTFE, so the transition will be smooth and end users will not be left at risk for lack of supply.